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HEC Pharm Co., Ltd. and HEC Pharm USA Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

BOEHRINGER INGELHEIM
PHARMACEUTICALS INC., BOEHRINGER
INGELHEIM INTERNATIONAL GMBH,
BOEHRINGER INGELHEIM
CORPORATION, AND BOEHRINGER
INGELHEIM PHARMA
GMBH & CO. KG,

Plaintiffs,

v.

HEC PHARM CO., LTD., HEC PHARM USA,
MYLAN PHARMACEUTICALS INC.,
MYLAN INC., MYLAN LABORATORIES
LIMITED, ACCORD HEALTHCARE, INC.,
AUROBINDO PHARMA LIMITED,
AUROBINDO PHARMA USA, INC., DR.
REDDY'S LABORATORIES, LTD., DR.
REDDY'S LABORATORIES, INC., ZYDUS
PHARMACEUTICALS USA, INC., CADILA
HEALTHCARE LTD., MSN
LABORATORIES PRIVATE LIMITED, MSN
PHARMACEUTICALS, INC., PRINSTON
PHARMACEUTICAL INC., INVAGEN
PHARMACEUTICALS INC., SUN
PHARMACEUTICAL INDUSTRIES LTD.,
SUN PHARMA GLOBAL FZE, SUN
PHARMACEUTICAL INDUSTRIES, INC.,
TEVA PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No. 3:15-cv-05982-PGS-TJB

FILED UNDER SEAL

**DEFENDANT HEC PHARM CO., LTD. & HEC PHARM USA INC.'S
BRIEF IN SUPPORT OF MOTION FOR RELIEF**

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[REDACTED]

[REDACTED]

I. INTRODUCTION & SUMMARY

Defendants HEC Pharm Co., Ltd. and HEC Pharm USA Inc. (collectively, “HEC” or “Defendants”) respectfully move pursuant to [REDACTED]

[REDACTED] Plaintiffs here are Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; Boehringer Ingelheim Corporation; and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, “Boehringer” or “Plaintiffs”). [REDACTED]

[REDACTED] (attached hereto as Exhibit A of the Declaration of C. Klingman (“Klingman Decl.”), submitted herewith).

[REDACTED] the two products that were the subject of this case: linagliptin (brand name “Tradjenta®”) and linagliptin+metformin hydrochloride (brand name “Jentadeuto®”).¹ See Exh. A. [REDACTED]

[REDACTED], as will be explained herein.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

On the bases explained below, HEC respectfully requests entry of this requested relief.

II. STATEMENT OF FACTS

A. **Boehringer Sued HEC, Among Others, for Patent Infringement on TRADJENTA® and JENTADUETO® (linagliptin and linagliptin and metformin hydrochloride).**

Boehringer manufactures and markets Tradjenta® brand linagliptin tablets² and Jentadueto® brand linagliptin and metformin tablets³ (“the *Boehringer Products*”). Exh. A at 1. In 2015, HEC filed an Abbreviated New Drug Application (“ANDA”) related to Tradjenta®, seeking FDA approval to engage in manufacture, use, or sale of tablets containing linagliptin⁴ and containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“P-IV Certification”) regarding *Boehringer’s* ‘955, ‘648, ‘541, ‘927, and ‘156 patents.⁵ In 2016, HEC filed a

² This was authorized by the U.S. Food and Drug Administration (the “FDA”) under approved New Drug Application (“NDA”) No. 201280.

³ This was authorized by the U.S. FDA under approved NDA No. 201281.

⁴ ANDA No. 208335 (the “HEC LINA ANDA”).

⁵ Klingman Decl., Exh. B (ANDA Cover Letter) & Exh. C (Notice Letter).

supplemental P-IV Certification for the '859 patent, and in 2017, HEC filed a second supplemental P- IV Certification for the '526 patent.⁶ HEC also filed an ANDA related to the Jentaduetto® product, which is a tablet combining linagliptin and metformin hydrochloride.⁷ As part of that filing, HEC filed P-IV Certifications for the '955, '648, '541, and '927 patents in 2015, and the '859 patent in 2016.⁸

Other companies filed ANDAs on the same products. One, Zydus Pharmaceuticals USA, Inc. (along with a related party, Cadila Healthcare Ltd.) (hereinafter "Zydus"), filed an ANDA containing a P-IV certification on the same patents as HEC. Dkt. 1 (Complaint), ¶¶ 401, 406. The other filers did not file P-IV certifications against the '955, '648, and '541 patents.

On August 4, 2015, Boehringer filed suit in this Court against a number of generic companies, including HEC. Dkt. 1. As to HEC and Zydus, Boehringer alleged infringement of the '955, '648, '541, '927 and '156 patents. *See* Dkt. 1; Dkt. 6 (Amended Complaint).⁹ As to the other defendants, Boehringer asserted infringement of the patents upon which those defendants had made P-IV certifications, including the '927 and '156 patents.¹⁰ In 2016, Boehringer filed suits in this Court against the same generic pharmaceutical companies asserting infringement of the '859 patent.¹¹

On December 8, 2016, this Court granted a Motion to Dismiss with respect to the asserted claims of the '156 patent, finding them invalid under 35 U.S.C. § 101. *See* Dkt. 388.

⁶ Klingman Decl., Exh. D (2016 Notice Letter) & Exh. E (2017 Notice Letter).

⁷ ANDA No. 208336 (the "HEC LINA/MET ANDA"); Klingman Decl., Exh. F (ANDA Cover Letter).

⁸ Klingman Decl., Exh. G (2015 Jentaduetto Notice Letter) & Exh. H (2016 Jentaduetto Notice Letter).

⁹ These complaints also asserted one additional patent, U.S. Pat. No. 8,846,695. But Boehringer later disclaimed its rights to enforce this patent, and it was not further asserted in the litigation.

¹⁰ *See* note 9, *supra*.

¹¹ *See, e.g.*, Dkts. 1, 15 in Civil Action No. 3:16-cv-000852-PGS-TJB; Dkts. 1, 8 in Civil Action No. 3:16-cv-01727-PGS-TJB; Dkt. 1 in Civil Action No. 3:16-cv-02394-PGS-TJB.¹¹ All three actions were consolidated with this action. *See* Dkt. 11 in Civil Action No. 3:16-cv-000852-PGS-TJB; Dkt. 16 in Civil Action No. 3:16-cv-01727-PGS-TJB; Dkt. 11 in Civil Action No. 3:16-cv-02394-PGS-TJB.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

After Boehringer settled with HEC, it continued litigation against the remaining defendants. However, it later settled with Zydus, and a consent judgment was entered as to Zydus on May 29, 2018. Dkt. 546. Thereafter, then, the only claims asserted against the remaining parties were those of the '927 and the '859 patents, with Boehringer also reserving the right to appeal the decision invalidating the asserted claims of the '156 patent.

[REDACTED]

On October 15, 2018, this Court issued a Final Judgment, finding the asserted claims of the '927 and '859 patents invalid. Dkts. 619, 620. Boehringer appealed this Court's holdings of invalidity with respect to the asserted claims of those patents, and with respect to the asserted claims of the '156 patent. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

III. LEGAL STANDARD

A. This Court Has Authority [REDACTED]

This Court has authority and jurisdiction to consider this matter and to grant the requested relief. [REDACTED]

[REDACTED]

[REDACTED]

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IV. ARGUMENT

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B. HEC Is Entitled To The Requested Relief

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thus, HEC is entitled to an order from this Court [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

V. CONCLUSION

On the basis of the foregoing, Defendant HEC respectfully requests this Court [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dated: May 21, 2020

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